REMARKS

Examiner Interview Summary

Pursuant to Rule 133(b), Applicants acknowledge with gratitude the interview of January 8, 2008, conducted between Applicants' representative, Siegfried J. Ruppert, and Examiner Minh-Tam DAVIS. During the interview, Applicants' representative and Examiner Davis discussed the grouping of claims 1-25 into 34 groups as detailed in the Office Action mailed August 09, 2007. Specifically, groups 1-5 were discussed. Applicants' representative pointed out that Applicants discovered that cancers examined showed methylation of the SOCS-3 promoter within SEQ ID NO:3 and that SOCS-3 promoter methylation led to the silencing of expression of a SOCS-3 nucleic acid (SEQ ID NO:1), which ultimately led to the low level or no detectable expression of a SOCS-3 polypeptide (SEQ ID NO:2). Thus, cancers examined by Applicants which show a decreased expression of SOCS-3 also show methylation of the SOCS-3 promoter. Examiner Davis suggested to include an appropriate limitation in claim 1 which would provide a common technical relationship and thereby combine groups 1-5 into a new group. Examiner Davis indicated she would consider such an amendment, however, would have to review the amendment in more detail before allowing the combining of groups 1-5 into a single group.

Amendments to the Claims

Applicants have amended claim 1 to include the limitation "wherein the cancer is characterized by having a methylation of a SOCS-3 promoter." Support for this amendment can be found in the specification, e.g., in Figs. 1-4 and 7, paragraphs [0006], [0017] - [0020], and [0023], and claims 7-11 as originally filed.

New claims 26-31 have been added. Support for new claims 26-28 can be found in the specification, e.g., in paragraphs [0019], [0101] - [0102], and in Figure 3. Support for new claim 29 can be found, e.g., in paragraphs [0103] - [0105] and in Figures 1 and 6. Support for new claim 30 can be found in paragraphs [0017] and [0177] and in Figure 1. Support for new claim 31 can be found, e.g., in claim 8 as originally filed.

No new matter has been added by these amendments.

Response to Election/Restriction Requirement

This communication is responsive to an Office Action mailed on August 9, 2007 and requesting the election of a group. In this Office Action, the Examiner argued that claims 1-25 as filed are not so linked as to form a single general inventive concept under PCT Rule 13.1 and argued that claims 1-25 correspond to 34 distinct inventions:

Group 1 (claims 1-3 and 12), drawn to a method for detecting lung cancer by detecting the level of the nucleic acid SEQ ID NO:1;

Groups 2-5 (claims 1-3 and 12), drawn to a method for detecting breast cancer, mesothelioma, colon cancer or sarcoma by detecting the level of the nucleic acid SEQ ID NO:1;

Groups 6-10 (claims 4-6 and 12), drawn to a method for detecting lung cancer, breast cancer, mesothelioma, colon cancer or sarcoma by detecting the level of the polypeptide SEQ ID NO:2;

Groups 11-15 (claims 7-11 and 13), drawn to a method for detecting lung cancer, breast cancer, mesothelioma, colon cancer or sarcoma by detecting the methylation of the promoter SEQ ID NO:3;

Group 16 (claims 14-16), drawn to a method for screening an agent that increases SOCS-3 activity, using SOCS-3 promoter;

Group 17 (claims 14-15 and 17), drawn to a method for screening an agent that increases SOCS-3 activity, using SOCS-3 mRNA transcript;

Group 18 (claims 14-15 and 18), drawn to a method for screening an agent that increases SOCS-3 activity, using SOCS-3 polypeptide;

Groups 19-23 (claims 19-24), drawn to a method for treating lung cancer, breast cancer, mesothelioma, colon cancer or sarcoma using the SOCS-3 nucleic acid SEQ ID NO:1;

Groups 24-28 (claims 19-21 and 23), drawn to a method for treating lung cancer, breast cancer, mesothelioma, colon cancer or sarcoma using SEQ ID NO:2;

Groups 29-33 (claims 19-21 and 24), drawn to a method for treating lung cancer, breast cancer, mesothelioma, colon cancer or sarcoma using a demethylation agent; and

Group 34 (claim 25), drawn to a kit comprising primers from SEQ ID NO:3.

According to the Examiner, with respect to Groups 1-15, and 19-33, each cancer constitutes a single, distinct invention.

According to the Examiner, with respect to Groups 16-18, each step of determining SOCS-3 activity constitutes a single, distinct invention.

Initially, Applicants wish to point out that claims 19-24 as filed are not directed, to a method for treating cancer, but rather to a method of inhibiting proliferation of a cancer cell.

Applicants respectfully traverse the Examiner's determination of Groups 1-34.

Unity of Invention

Applicants concurrently submit an Information Disclosure Statement (IDS) including copies of the (i) International Preliminary Report on Patentability, (ii) Written Opinion of the International Searching Authority , and (iii) International Search Report. Applicants wish to point out that according to these documents, claims 1-25 as searched do not lack unity of invention.

Applicants have discovered for the first time that cancers examined have low or no detectable expression of the SOCS-3 nucleic acid (SEQ ID NO:1) or SOCS-3 protein (SEQ ID NO:2) as a result of methylation of a SOCS-3 promoter:

> "This invention is based on the discovery that frequent hypermethylation in CpG islands of the functional SOCS-3 promoter correlates with its transcription silencing in cancer. The invention thus provides methods of diagnosing cancer based on detecting the presence of hypermethylation in the SOCS-3 promoter and/or detecting a decrease in the level of SOCS-3 mRNA or protein." ([**0006**])

While Applicants' specification discloses this common finding for many cancers, including lung cancer, breast cancer, colorectal cancer, sarcoma, mesothelioma, prostate cancer, pancreatic cancer, cervical cancer, ovarian cancer, gastric cancer, esophagal cancer, head and neck cancer, hepatocellular carcinoma, melanoma, glioma, or glioblastoma (e.g., [0006], [0010], [0016]), Applicants describe in detail the experimental analysis of several cancers, including lung cancers, breast cancers, and mesothelioma (e.g., Figs. 1-9 and Examples 1-4). In these

cancers, Applicants found that cancers which have a reduced expression of SOCS-3 nucleic acid (SEQ ID NO:1) also have methylation within the SOCS-3 promoter (SEQ ID NO:3). As such, there is a technical relationship among Applicants' inventions involving one or more of the same or corresponding special technical features. (37 CFR 1.475(a)). Applicants have amended claim 1 to more clearly point out this technical relationship.

Election of Group

In view of the interview with Examiner Davis and arguments provided herein, Applicants herewith elect claims 1-3 and 12 (formerly grouped into groups 1-5), drawn to a method for detecting cancer by detecting the level of the nucleic acid SEQ ID NO:1.

Status of Claims

Claims 1-3, 12, and 26-31 encompass the elected invention and are presented for examination. Claims 4-11 and 13-25 are cancelled herewith.

Request for Refund of Excess Claims Fees Paid

Applicants have cancelled claims 4-11, and 13-25 (six (6) independent claims and fifteen (15) dependent claims). Applicants have added six (6) new dependent claims (claims 26-31). Applicants request a refund of excess claims fees paid. (37 CFR § 1.117).

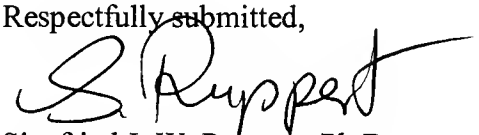
CONCLUSIONS

Applicants believe that no fee is required. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition of allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephonic conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200

Respectfully submitted,



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